February 5, 2024

Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

RE: HTI-1 Final Rule Timeline for DSI

Dear Dr. Tripathi,

On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we wish to discuss the recently finalized and published *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) rule*. Our members are diligently reviewing these final requirements and compiling detailed feedback and requests for clarification, which we will present to the ONC shortly.

In the interim, we have a few domains of immediate concern. First, the final rule sets a deadline of December 31, 2024, for Decision Support Interventions (DSI). Affected certified health IT developers must develop and "provide" (as defined by ONC at 45 CFR 170.102) the capabilities under the newly adopted DSI criterion under the Assurances Maintenance of Certification requirements at 45 CFR 170.402(b). Second, we are concerned about the timelines established by ONC for health IT developers and how these affect provider usage under recent CMS regulations. We will detail these concerns in a separate letter to ONC and CMS.

The EHR Association would like first to express our appreciation to the ONC for its approach in finalizing the DSI requirements. This approach, which narrows the scope in some critical areas, reflects a thoughtful consideration of our feedback on the DSI proposals from the HTI-1 notice of proposed rulemaking. Overall, the finalized scope of requirements is more appropriate and realistic for certified health IT developers, aiding the industry in making meaningful strides toward the adoption of trustworthy AI.

AdvancedMD	CureMD	Flatiron Health	MEDITECH, Inc.	Oracle Health
Allscripts	eClinicalWorks	Foothold Technology	Modernizing Medicine	PointClickCare
Altera Digital Health	Elekta	Greenway Health	Netsmart	Sevocity
Athenahealth	EndoSoft	Harris Healthcare	Nextech	STI Computer Services
BestNotes	Epic	MatrixCare	NextGen Healthcare	Varian – A Siemens Healthineers Company
CPSI	Experity	MEDHOST	Office Practicum	

Though we appreciate the reduced scope of the finalized requirements, it is important to note that they still represent substantial net-new development efforts for affected certified health IT developers. This includes development in novel areas for the program, including AI/ML for predictive DSIs. Below is a brief breakdown of these work efforts, outlining their impact on developers.

- **Development of an end-user feedback function for evidence-based DSIs, including an export capability for machine-readable formatted feedback data (170.315(b)(11)(ii)(C)).** This is expected to necessitate development work, including possible new data models for storage of feedback information and design strategy work for the presentation of feedback opportunities to end users.

- **Development of support for a significantly expanded set of data concepts for which selection of evidence-based DSIs must be available (170.315(b)(11)(iii)(A)).** Specifically, this includes supporting selection of evidence-based DSIs for every U.S. Core Data for Interoperability (USCDI) data element under the cited data classes, which constitutes an expansion of ~27 new data elements for USCDI v3 when compared to the current requirement under the Clinical Decision Support criterion. We acknowledge that some of those new data elements would not be required until December 31, 2025, based on the corresponding dates for advancement to version 3 of USCDI under the standard at 170.213. However, this will still require significant development work for what is required by December 31, 2024.

- **Development of support for enabling selection of predictive DSIs using any data expressed in the USCDI (170.315(b)(11)(iii)(B)).** This is anticipated to entail significant development work.

- **Production of nine new source attribute data points for all evidence-based DSIs that developers supply, and over 30 source attribute data points for all predictive DSIs that developers supply (170.315(b)(11)(iv)).** This necessitates administrative time and effort to produce the source attribute information across all supplied DSIs.

- **Development of support for accessing and modifying source attribute information provided by developers for those DSIs they supply (170.315(b)(11)(v)).** This requires not only development work but also considerable strategic planning in terms of how and where to integrate the information within the system to optimally meet user requirements.

- **Development of support for enabling customers to record and modify their own source attribute entries in the system for DSIs they create or implement on their own (170.315(b)(11)(B)).** This also necessitates development work and significant strategic design considerations for how and where to provide the information within the system to meet user requirements.

- **Development of detailed intervention risk management policies and procedures for ongoing management of predictive DSIs supplied by developers (170.315(b)(11)(vi)).** This necessitates significant administrative and procedural time and effort to establish well-defined and reliable policies and procedures that align with ONC's framework.

The EHR Association recognizes ONC's position as expressed in the HTI-1 final rule preamble that the lengthened timelines for other requirements adopted in the final rule should provide developers with the ability to prioritize the DSI updates to meet the December 31, 2024 deadline. However, the fact remains that even with those other extensions, the significant work outlined above is nonetheless a formidable challenge to deliver in a valuable, user-friendly manner within the 12-month timeframe allotted in the rule.

This challenge is amplified when considering that, under current CMS requirements for provider use of certified health IT, developers would need to provide the updates well in advance of the ONC's deadline to facilitate our customers' compliance. Additionally, the extended deadlines for other requirements may not provide the intended relief, as customers may demand that developers release all capabilities simultaneously to avoid multiple system upgrades that could disrupt and add undue stress to their operations.
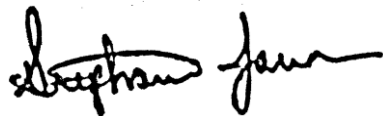
Finally, it is crucial to note that in many instances, developers are currently prevented from commencing development work, as there is not a published certification companion guide (CCG) or other resource guide to provide necessary guidance and clarifications for developers on the DSI requirements. This delay contributes heavily to the challenge of meeting the imposed deadline, as such guides provide crucial input for defining the development's design and scope.

Ultimately, maintaining the current DSI criterion deadlines will inevitably result in rushed development that fails to achieve the goals of ONC's adopted requirements.

The EHR Association strongly urges ONC to consider implementing a 6-12-month enforcement discretion for the adopted DSI deadline. This approach would ensure that there is meaningful progress made toward real-world implementation of the DSI provisions by the adopted December 31, 2024 deadline without imposing upon certified health IT developers an understandable inability to meet unrealistic regulatory deadlines.

We welcome the opportunity for ongoing discussion. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org.

Sincerely,

Stephanie Jamison
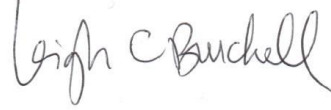Chair, EHR Association
Greenway Health

William J. Hayes, M.D., M.B.A.
Vice Chair, EHR Association
CPSI

HIMSS EHR Association Executive Committee
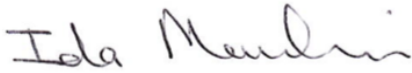
David J. Bucciferro
Foothold Technology

Leigh Burchell
Altera Digital Health

Danielle Friend
Epic

Cherie Holmes-Henry
NextGen Healthcare

Ida Mantashi
Modernizing Medicine

Kayla Thomas
Oracle Health